CLAIMS

1-70. (cancelled).

71. (currently amended) A controlled release methylphenidate tablet ~~comprising~~ consisting of:

(A) an immediate release methylphenidate coating comprising;

(a) methylphenidate or a pharmaceutically acceptable salt or isomer thereof;

(b) a binder; and

(c) optionally a stabilizer;

(B) a controlled release methylphenidate core tablet ~~comprising~~ consisting of:

(a) a compressed mixture comprising:

(i) methylphenidate or a pharmaceutically acceptable salt or isomer thereof;

(ii) 1 to about 50% of the total weight of the compressed mixture of a hydrogel polymer; ~~and~~

(iii) a diluent; and

(iv) optionally a lubricant; and

(b) an enteric coating surrounding the compressed mixture comprising;

(i) 45-80 weight percent based upon the total weight of the enteric coating of at least one enteric polymer; and

(ii) at least one conventional processing aid; and

(C) optionally an aesthetic coating

wherein the controlled release methylphenidate tablet exhibits the following dissolution profile when tested in a United States Pharmacopoeia type 2 (paddle) apparatus at 50 rpms in 900 ml of phosphate buffer with a pH of 7.5 and at 37°C:

1-35% of the methylphenidate is released after 1 hour;

5-40% of the methylphenidate is released after 2 hours;

and not less than 70% is release after 10 hours and when administered to humans exhibits a plasma peak for the immediate release layer (T_{max1}) between 1 and 5 hours, a plasma peak for the controlled release core (T_{max2}) between 4 and 12 hours, and a plasma trough (T_{min}) between 2 and 7 hours in between the two peak plasma levels~~; and~~

~~wherein said tablet exhibits an in vitro curve similar to that shown in Figure 6.~~

72. (currently amended) The controlled release methylphenidate tablet as defined in claim 71 wherein the controlled release tablet releases: 42-53% of the methylphenidate after 4 hours of testing in a United States Pharmacopeia type 1 apparatus at 100 rpms in 500 ml of phosphate buffer with a pH of 7.5 and at 37°C and 67-81% of the methylphenidate after 6 hours of testing in a United States Pharmacopeia type 1 apparatus at 100 rpms in 500 ml of phosphate buffer with a pH of 7.5 and at 37°C.

73. (previously presented) The controlled release methylphenidate tablet as defined in claim 71 wherein the hydrogel polymer in the compressed mixture is selected from the group consisting of methyl cellulose, hydroxymethyl cellulose, polyvinyl pyrrolidone, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene oxides, gums, acrylate polymers and methacrylate polymers.

74. (previously presented) The controlled release methylphenidate tablet as defined in claim 71 wherein the enteric polymer is selected from a group consisting of zein, methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate trimellitate, shellac, polyvinyl acetate phthalate or mixtures thereof.

75. (previously presented) The controlled release methylphenidate tablet as defined in claim 71 wherein the T_{max1} occurs less than 3 hours and declines in less than 5 hours.

76. (previously presented) The controlled release methylphenidate tablet as defined in claim 71 wherein the T_{max2} occurs about 7 to 9 hours and declines to about 1.4 ng/ml in about 14 to 18 hours.

77. (currently amended) A controlled release methylphenidate tablet as defined in claim 71 consisting ~~essentially~~ of:

(A) an immediate release methylphenidate coating consisting essentially of;

(a) 30-60 weight percent based upon the total weight of the immediate release coating of methylphenidate or a pharmaceutically acceptable salt or isomer thereof;

(b) 40-70 weight percent based upon the total weight of the immediate release coating of a binder; and

(c) 0.005-5 weight percent based upon the total weight of the immediate release coating of a stabilizer;

(B) a controlled release methylphenidate core tablet consisting ~~essentially~~ of:

(a) a compressed mixture consisting essentially of:

(i) 5-40 weight percent based upon the total weight of the compressed mixture of methylphenidate or a pharmaceutically acceptable salt or isomer thereof;

(ii) 3-40 weight percent based upon the total weight of the compressed mixture of a hydrogel polymer;

(iii) 25-90 weight percent based upon the total weight of the compressed mixture of a diluent; and

(iv) 0.1-10 weight percent based upon the total weight of the compressed mixture of a lubricant ~~an anti-sticking agent~~; and

(b) an enteric coating surrounding the core tablet consisting essentially of;

(i) 45-80 weight percent based upon the total weight of the enteric coating of at least one enteric polymer;

(ii) 0.5-15 weight percent based upon the total weight of the enteric coating of a plasticizer; ~~and~~

(iii) an anti-sticking agent; and

(iv) optionally a surfactant; and

(C) optionally an aesthetic coating

~~wherein the controlled release methylphenidate tablet exhibits the following dissolution profile when tested in a United States Pharmacopeia type 2 (paddle) apparatus at 50 rpms in 900 ml of phosphate buffer with a pH of 7.5 and at 37°C:~~

~~1-35% of the methylphenidate is released after 1 hour; 5-40% of the methylphenidate is released after 2 hours; and not less than 70% is release after 10 hours and when administered to humans exhibits a plasma peak for the immediate release layer (T_{max1}) between 1 and 5 hours, a plasma peak for the controlled release core (T_{max2}) between 4 and 12 hours, and a plasma trough (T_{min}) between 2 and 7 hours in between the two peak plasma levels~~.

78. (currently amended) The controlled release methylphenidate tablet as defined in claim 71 ~~77~~ wherein:

(A) the immediate release methylphenidate coating consists ~~essentially~~ of;

(a) 40-50 weight percent based upon the total weight of the immediate release coating of methylphenidate or a pharmaceutically acceptable salt or isomer thereof ;

(b) 45-60 weight percent based upon the total weight of the immediate release coating of a binder; and

(c) 0.01-2 weight percent based upon the total weight of the immediate release coating of a stabilizer;

(B) the controlled release methylphenidate core tablet consists ~~essentially~~ of:

(a) a compressed mixture consisting ~~essentially~~ of:

(i) 10-25 weight percent based upon the total weight of the compressed mixture of methylphenidate or a pharmaceutically acceptable salt or isomer thereof;

(ii) 3-40 weight percent based upon the total weight of the compressed mixture of a hydrogel polymer;

(iii) 45-85 weight percent based upon the total weight of the compressed mixture of a diluent; and

(iv) 0.5-5 weight percent based upon the total weight of the compressed mixture of a lubricant ~~an anti-sticking agent~~; and

(b) an enteric coating surrounding the core tablet consisting ~~essentially~~ of;

(i) 45-80 weight percent based upon the total weight of the enteric coating of at least one enteric polymer;

(ii) 1-5 weight percent based upon the total weight of the enteric coating of a plasticizer; ~~and~~

(iii) an anti-sticking agent; and

(iv) optionally a surfactant.

79. (new) The controlled release tablet of claim 71 wherein the enteric coating surrounding the compressed mixture comprises zein and at least one additional enteric polymer.

80. (new) The controlled release tablet of claim 79 wherein the at least one additional enteric polymer is a methacrylic acid copolymer.

81. (new) A controlled release methylphenidate tablet consisting of:

(A) an immediate release methylphenidate coating comprising;

(a) methylphenidate or a pharmaceutically acceptable salt or isomer thereof;

(b) a binder; and

(c) optionally a stabilizer;

(B) a controlled release methylphenidate core tablet consisting of:

(a) a compressed mixture comprising:

(i) methylphenidate or a pharmaceutically acceptable salt or isomer thereof;

(ii) 1 to about 50% of the total weight of the compressed mixture of a hydrogel polymer selected from the group consisting of methyl cellulose, hydroxymethyl cellulose, polyvinyl pyrrolidone, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene oxides, gums, acrylate polymers and methacrylate polymers;

(iii) a diluent; and

(iv) optionally a lubricant; and

(b) an enteric coating surrounding the compressed mixture consisting of:

(i) 45-80 weight percent based upon the total weight of the enteric coating of at least one enteric polymer selected from a group consisting of zein, methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate trimellitate, shellac, polyvinyl acetate phthalate or mixtures thereof; and

(ii) one or more conventional processing aids selected from the group consisting of a plasticizer, surfactant, anti-sticking agent or mixtures thereof; and

(C) optionally an aesthetic coating

wherein the controlled release methylphenidate tablet exhibits the following dissolution profile when tested in a United States Pharmacopoeia type 2 (paddle) apparatus at 50 rpms in 900 ml of phosphate

buffer with a pH of 7.5 and at 37°C:

1-35% of the methylphenidate is released after 1 hour;

5-40% of the methylphenidate is released after 2 hours;

and not less than 70% is released after 10 hours;

42-53% of the methylphenidate is released after 4 hours of testing in a United States Pharmacopeia type 1 apparatus at 100 rpms in 500 ml of phosphate buffer with a pH of 7.5 and at 37°C and 67-81% of the methylphenidate is released after 6 hours of testing in a United States Pharmacopoeia type 1 apparatus at 100 rpms in 500 ml of phosphate buffer with a pH of 7.5 and at 37°C and when administered to humans exhibits a plasma peak for the immediate release layer (T_{max1}) between 1 and 5 hours, a plasma peak for the controlled release core (T_{max2}) between 4 and 12 hours, and a plasma trough (T_{min}) between 2 and 7 hours in between the two peak plasma levels.

82. (new) The controlled release tablet of claim 81 wherein the enteric coating surrounding the compressed mixture comprises zein and at least one additional enteric polymer.

83. (new) The controlled release tablet of claim 82 wherein the at least one additional enteric polymer is a methacrylic acid copolymer.

84. (new) The controlled release methylphenidate tablet as defined in claim 81 wherein the T_{max2} occurs about 7 to 9 hours and declines to about 1.4 ng/ml in about 14 to 18 hours.